LOOKING AHEAD

The new year is a good time to take stock and try, as best we can, to map out our way forward for 1997. *Bandolier* has a number of good intentions for the year ahead.

Evidence of effectiveness

Bandolier plans to continue carrying information on systematic reviews of evidence of effectiveness. Because more are appearing, it should be easier in future than it has been in the past. Regular searches of MEDLINE, for instance, can help, as well as other sources like the Cochrane Library and DARE.

There will be problems, for instance where reviews fail to find randomised trials, so that even though you may have asked for evidence on a topic, the highest quality evidence just isn't available.

Spinal cord stimulators

Take spinal cord stimulators. *Bandolier* has been asked for evidence on this. A review exists [1], but failed to find any randomised trials. Turner, Loeser and Bell conducted a thorough literature search in an attempt to determine the place of SCS in chronic pain treatment.

They included 39 studies, but none was randomised: all were case series. A majority (82%) did not have planned study protocols. The review does not give the total number of patients treated or reported. Few studies define patient inclusion or exclusion criteria, or give demographic information on patients treated. The source of follow-up data was unclear in most of the studies.

Twenty-nine studies had at least 50% pain relief as an outcome. Across these studies the mean (probably unweighted, but not stated) was 59% of patients achieving this outcome at some follow-up point, with a range of 15% to 100%. Fourteen studies reporting one year follow up with success defined as stimulator in use with at least 50% pain relief. In these, the mean across study success rate was 62%, again with a range of 15% to 100%.

Fewer studies reported success at later follow up times. At two years five trials reported a mean of 64% success (range 55% to 74%). At five years three studies reported a mean of 53% success (range 50% to 55%). At ten years one study reported 35% success.

Complications were common. In 13 studies any complication occurred in 42% of patients (range 20% top 75%). These were predominantly stimulator or electrode problems (mean 30% and 24% respectively, range 0% to 75%). Infection was less common, occurring in 5% of patients in 20 trials that reported it (range 0% to 12%). Most complications appeared to be minor.

So we have interesting information, but no real certainty that it is right.

Diagnostic tests

Bandolier seeks reviews and insight on these. Few exist, though one is reported this month. We continue, though, to be intrigued by the triumph of simple clinical scoring over laboratory technology. One example (that of alcoholic cirrhosis) this month is obvious, but the underwhelming ability of the biochemistry to make the diagnosis is fascinating, especially when highly publicised court cases make life-turning decisions based on some laboratory estimations.

Help wanted

Bandolier continues to be impressed by the searching questions posed by its readers, but is struck by how few of you see reviews (or other sources of evidence) you feel sufficiently important to ask *Bandolier* to carry so that others can benefit. Your help is requested in 1997 to bring to *Bandolier's* attention evidence worthy of trumpeting abroad.

Using reviews

One reader, recently awakened to *Bandolier's* usefulness, has asked for us to revisit NNT calculations, and how to make the best of a systematic review. This year we will try to find a review which will enable us to 'walk you through' the process and calculations.

Reference:

1   JA Turner, JD Loeser, KG Bell. Spinal cord stimulation for chronic back pain: a systematic literature synthesis. Neurosurgery 1995 37: 1088-96.

*The views expressed in **Bandolier** are those of the authors, and are not necessarily those of the NHSE Anglia & Oxford*

HORMONAL IUD

Bandolier has been asked by GPs about the effectiveness and cost effectiveness of the Mirena® IUD device sold in the UK by Pharmacia-Leiras. Here we examine trials of effectiveness, but as explained below, we duck the question of cost.

Mirena

The Mirena system is a plastic T-shaped frame with a steroid reservoir containing 52 mg levonorgestrel (LNG) designed to release about 20 µg LNG per day. It is a minor variant of a previous device (LNG 20)

How it works

The contraceptive device delivers LNG to the endometrium after insertion. This makes the endometrium unresponsive to oestradiol. The endometrium becomes inactive and atrophic so that menstrual shedding is reduced. The inactive endometrium also produces less prostaglandin, so dysmenorrhoea is also reduced. Changes in the endometrium take place irrespective of ovarian function and are a result of the local action of LNG. Thickening of cervical mucus also occurs, making penetration of sperm less likely.

Randomised trials

There are four randomised trials which compare the LNG 20 µg/day intrauterine system (IUS), the precursor of Mirena, with other IUDs. All trials were open, and used copper IUDs for comparison; two [1,2], each of 5-years duration, used the Nova T and two, one of 7-years duration [3] and the other of 3-years [4], the TCu 380 Ag.

Because trials have reported at various stages, *Bandolier* has taken the longest time period available, though the device has a three year licence in the UK. The most thorough report [1] is examined in detail, with information from others as appropriate. There is also a useful review of the trials [5].

Contraceptive effectiveness

The gross cumulative pregnancy rates in percentages are shown in the L'Abbé plot, together with the number of women in each trial using the LNG-20. The grouping of points, each of which represents one trial, below the line of equality shows that pregnancy rates with LNG-20 were consistently lower than control. This was statistically significant in three of the trials. The average pregnancy rate for all four trials was 0.6% at an average of five years. The review of four IUDs concluded that the LNG-20 was associated with the lowest pregnancy rates.

Ectopic pregnancy

Two studies reported ectopic pregnancy rates as events per 100 woman years. A rate of 0.02 per 100/woman years was found in [1], ten times less than the ectopic rate for Nova T. No ectopic pregnancies were reported in [3] with LNG-20, compared with a rate of 0.05/100 woman years for TCu 380 Ag.

Pelvic inflammatory disease

The same two trials reported the incidence of PID. In [1] the cumulative 5-year occurrence was 2.2% for Nova T and 0.8% for LNG-20. In the comparison with TCu 380 Ag [3] the rate per 100 woman years was the same, 0.7, in both groups.

Expulsion

There seems to be no real difference in expulsion rates.

Amenorrhoea

LNG-20 is associated with a higher rate of amenorrhoea than other IUDs (five-year cumulative rate of discontinuations in [1] of 6% for LNG-20 compared with 0% for Nova T), especially in younger women.
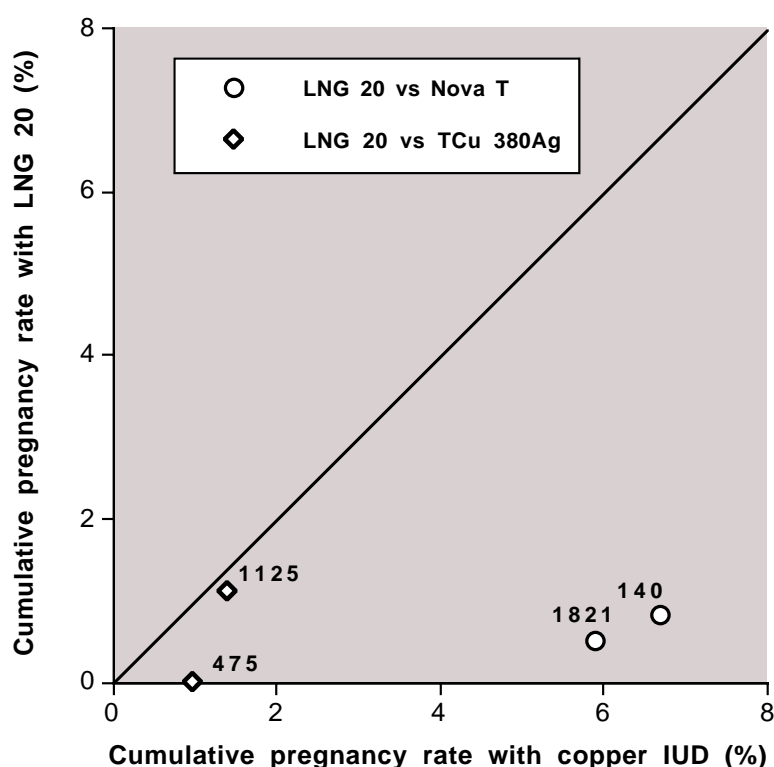
Hormonal effects

Because some steroid is absorbed into the circulation, there tends to be a higher rate of discontinuation with LNG 20 because of symptoms associated with contraceptive steroid use (12% compared with 2% in [1]).

Bleeding problems

Discontinuations with bleeding problems were significantly lower with LNG-20 (14% compared with 21% in [1]). The discontinuation rates over 5 years because of heavy or prolonged menstrual blood flow were very significantly lower with LNG-20. Moreover, because the mean number of days with bleeding fell to lower levels with LNG-20, haemoglobin levels rose in women on LNG-20 by 1.6 g/L after 5 years compared with a fall of 2.6 g/L in women using Nova T [1].

Pregnancy rates for LNG and copper IUDs in randomised trials

Cost effectiveness

Bandolier could find no information on cost effectiveness. Trying to compute it is no easy matter, and beyond *Bandolier's* resources. It will be a complex issue, with the much higher cost of the device (licensed for three years in the UK) set against lower costs from unwanted and ectopic pregnancy and better overall health gains.

References:
1 K Andersson, V Odlind, G Rybo. Levonorgestrel-releasing and copper-releasing (Nova T) IUDs during five years of use: a randomised comparative trial. Contraception 1994 49: 56-72.
2 T Luukkainen, H Allonen, M Laukkamaa et al. Five years' experience with levonorgestrel-releasing IUDs. Contraception 1986 33: 139-48.
3 I Sivin, J Stern. Health during prolonged use of levonorgestrel 20 μg/d and the copper TCu 380 Ag intrauterine contraceptive devices. Fertility and Sterility 1994 61: 70-7.
4 Indian Council of Medical research Task Force on IUDs. Randomised clinical trials with intrauterine devices: a 36-month study. Contraception 1989 39: 37-52.
5 I Chi. The TCu 380A (Ag), MLCu375 and Nova T IUDs and the IUD daily releasing 20 μg levonorgestrel - four pillars of IUD contraception for the nineties and beyond? Contraception 1993 47: 325-47.

WHICH PRIMARY TOTAL HIP REPLACEMENT?

A good question. In the UK, Murray and colleagues [1] have identified 62 different primary total hip replacements manufactured by 19 different companies. Half of these have been introduced in the last five years, and only 30% have any results published in peer-reviewed journals. Costs can range from £250 to £2000. The two cheapest implants have the longest follow up.

So what's the problem?

There are about 40,000 THRs carried out in the UK every year. The ideal is for the new joint to be put in and stay in without problems, but after 10 years about 10% of the joints do develop problems which necessitate a new operation and new joint. These revisions cost more, don't work as well or last as long as the primary THR. About 5,000 revision operations are done each year in the UK.

Long-term outcome becomes a major issue which determines overall cost and benefit. So much more so when devices are changed or improved.

What's the evidence

What evidence there is has been summarised in the review of all UK devices [1]. Five-year survival data were found for eight implants in peer-reviewed journal articles. For three there were ten-year survival results, for two 15-year survival results and for one 20-year survival results.

The two implants with more than 10-year results were the Charnley and Stanmore implants, which were amongst the cheapest.

Recommendations

In a thoughtful discussion, of interest to providers and purchasers, the authors make the following recommendations:

- Group A implants would be the small group with published long-term results that would allow patients, surgeons and purchasers to be reasonably confident that the implant is safe and will give reliable and reproducible results.

- Group B would include implants with good short-term published results, but in the transition to more formal EU directives on hip prostheses would include implants already available but with no published results. Surgeons may choose Group B implants for a variety of reasons, but it seems reasonable that purchasers and patients should be aware that there is uncertainty over their long-term reliability.

- Group C would comprise new implants which should be subject to some form of clinical testing as well as laboratory wear testing before being available, as modern prediction techniques should weed out those at high risk of failure.

Reference:
1 DW Murray, AJ Carr, CJ Bulstrode. Which primary total hip replacement? Journal of Bone and Joint Surgery 1995 77-B: 520-7.

WHICH LABORATORY SEROLOGY TEST FOR *H PYLORI*?

Meta-analysis of laboratory tests remains a rare bird, so it is particularly pleasing to see one which is of considerable relevance given the growing recognition of the importance of Helicobacter pylori infection for peptic ulcers and other disorders. Les Irwig and colleagues from Sydney [1] searched the literature for full papers and abstracts which examined the sensitivity and specificity of laboratory serology tests for the bacterium - but did not include near-patient blood tests.

Findings

They found 11 full papers and 10 abstracts which reported on 12 different tests - 11 of which were ELISA tests and one latex agglutination. Most were based on European subjects and predominantly used culture (with histology and urease testing) as the reference method.

Quality of studies was mixed. For instance, only eight of the 21 studies excluded patients recently treated with antibiotics (which can affect culture, but not serology tests because antibodies in the blood remain elevated for up to six months), and only three stated specifically that the study was appropriately blinded. Eight studies of 20 contained arithmetical errors and only four included results for every individual patient.

Results

There was no real difference in test accuracy between any of the methods. At a mean sensitivity of 85%, the overall specificity was 79%.

What do the results mean?

If you send a blood sample to a laboratory for detection of Helicobacter pylori antibodies, it really doesn't matter what test is used to detect the antibodies. There have been many circumstances in pathology where this hasn't been the case.

If you know the prevalence of Helicobacter infection in your population you can make a judgement about the predictive value of a positive or negative test from the table.

Predictive value of a test with 85% sensitivity and 79% specificity

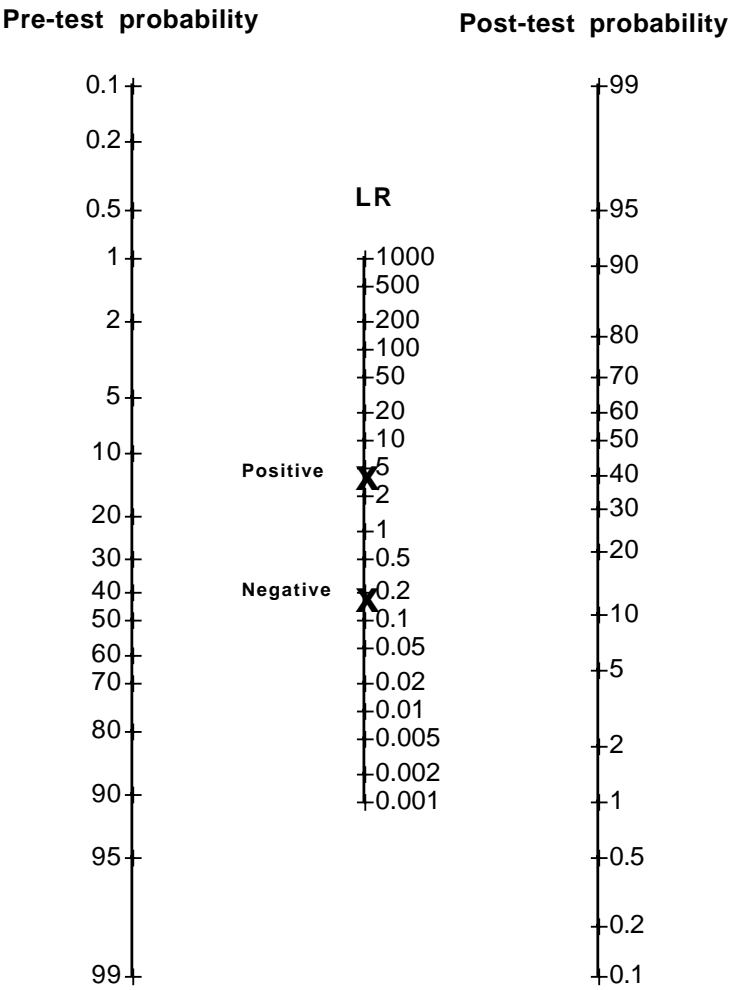| Prevalence of disease (%)	Probability of disease with a positive result (%)	Probability of disease with a negative result (%)
10	31	2
50	80	16
90	97	63

From these sensitivity and specificity data we can calculate the Likelihood Ratio (LR) for a positive and a negative test (see *Bandolier* 28). The LR for a positive test is 4 and for a negative test it is 0.2. These points are marked on the nomogram. For an individual patient, therefore, an assessment on clinical findings for the pre-test probability can be converted into the post-test probability of disease based on the result of the test.

If the test is positive run a line through the pre-test probability and the **X** marking 4 on the LR line to find the post-test probability. If it is negative run the line from the pre-test probability through the **X** marking 0.2.

Of course what is missing here is some guide as to clinical findings and ultimate diagnosis to help you. Since we don't have that guide, this is where clinical expertise and experience take over from evidence - or provide the best evidence available. This is important - a simple look at the nomogram will show that determining the pre-test probability of the disease is at least as important as the test result in determining the post-test probability.

Reference:
1   CT Loy, LM Irwig, PH Katelaris, NJ Talley. Do commercial serological kits for Helicobacter pylori infection differ in accuracy? A meta-analysis. American Journal of Gastroenterology 1996 91: 1138-44.

Pre-test probability

Post-test probability

LR

Pre-test	LR	Post-test
0.1		99
0.2		95
0.5		
1	1000	90
	500	
2	200	80
	100	
	50	70
5	20	60
	10	50
10	5 **X** Positive	40
	2	
20	1	30
30	0.5	20
40	0.2 **X** Negative	
50	0.1	10
60	0.05	
70	0.02	5
	0.01	
80	0.005	2
	0.002	
90	0.001	1
95		0.5
		0.2
99		0.1

CLINICAL SCORING FOR ALCOHOL ABUSE

The previous article on tests for antibodies to Helicobacter pylori, and previous examples on smoking (*Bandolier* 28) and urine testing (*Bandolier* 29) demonstrate the power of clinical history in generating high pre-test probability to exploit the additional power of a test. Of course, it's been said before and better. David Sackett and colleagues [1] put it like this (for clinical history of angina):

"Look at the relative size of the likelihood ratios for a brief, immediate, relatively cheap history and a much longer, delayed, and relatively expensive exercise electrocardiogram. There is no contest. Likelihood ratios for key points in the history and physical examination, both for this and for most other target disorders, are mammoth and dwarf those derived from most excursions through high technology."

A chastening thought for those of us who have been on a lifetime excursion through high technology. Yet frustratingly there are few examples with real data comparing clinical symptoms and eventual diagnosis by some gold standard.

Example from alcohol abuse

Patients can be screened systematically for drinking problems with a simple questionnaire. The CAGE questions are just four, scoring one point for each positive answer:

- Have you ever felt you should *Cut down* on your drinking?

- Have people *Annoyed* you by criticising your drinking?

- Have you ever felt bad or *Guilty* about your drinking?

- Have you ever had a drink first thing in the morning to steady your nerves or to get rid of a hangover (*Eye-opener*)?
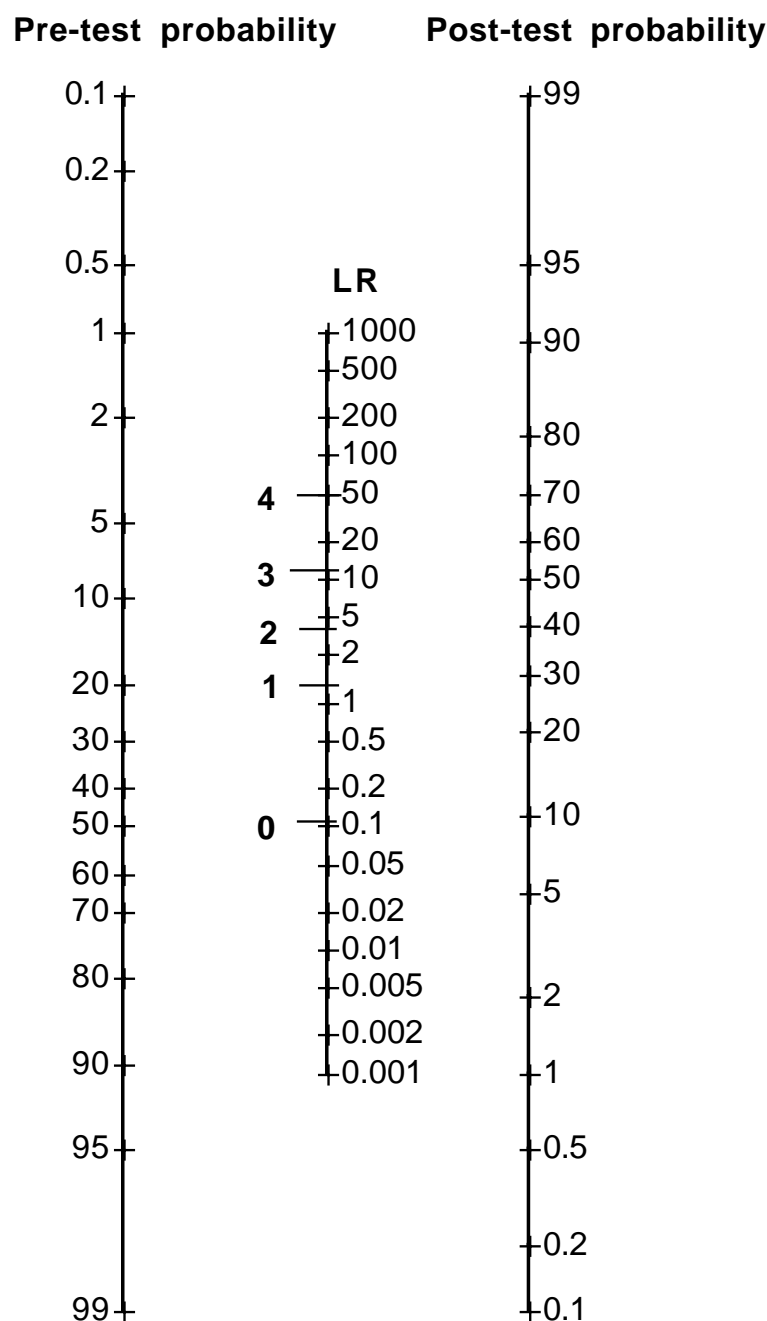
Likelihood ratios

Researchers in Virginia applied the questions to the outpatient medical practice aged over 17 of an urban teaching hospital [2]. Eight hundred and thirty six patients who met the inclusion criteria were asked to participate, and 98% agreed. Of these, 36% met criteria for a lifetime history of alcohol abuse or dependence using a gold standard instrument.

The results are shown in the table, with likelihood ratios calculated for patients who scored 0, 1, 2, 3, or 4 questions answered with yes. These can be used on the nomogram to help determine the post-CAGE probability of alcohol problems.

The pre-test probability is likely to have to come from prevalence figures. This might be known locally - but figures from the USA using the same gold standard instrument as in the paper suggests a prevalence of 25% for men and 4.5% for women [3]. These might be useful starting points for men and women.

Likelihood ratios with CAGE scores in 821 patients attending general medical outpatients

CAGE score	Alcoholic	Non-alcoholic	Likelihood ratio
0	33	428	0.14
1	45	54	1.50
2	86	34	4.50
3	74	10	13.00
4	56	1	100.00

Patients were defined as alcoholic or non-alcoholic according to Diagnostic and Statistical Manual of Mental Disorders criteria.

Clinical diagnosis of cirrhosis

Continuing the alcohol theme and the triumph of clinical observations over the laboratory, some Danish researchers [4] have shown that diagnosis of cirrhosis can be better made by clinical observation than by using biochemical tests.

Using data on over 300 alcohol-abusing men collected nearly 30 years ago, and with liver biopsy as the gold standard, they showed that facial telangiectasia, vascular spiders, white nails, abdominal veins, fatness and peripheral oedema could be used with high diagnostic accuracy. This was clearly superior to using biochemical variables of ESR, bilirubin, albumin, gamma globulin, liver enzymes and clotting factors.

The only problem is that the multiple logistic regression method they used is impenetrable to *Bandolier*. Perhaps one of our mathematically inclined readers can help.

References:
1   Clinical Epidemiology (Eds DL Sackett, RB Haynes, GH Guyatt, P Tugwell), 2nd Edition, 1991, 132.
2   DG Buchsbaum, RG Buchanan, RM Centor, SH Schnoll, MJ Lawton. Screening for alcohol abuse using CAGE scores and likelihood ratios. Annals of Internal Medicine 1991 115: 774-7.
3   G Edwards. Drug problems as everyday doctor's business. The Oxford Textbook of Medicine, 3rd Edition, 1996, 4263-5.
4   KJ Hamberg, B Carstensen, T Sørensen, K Eghøje. Accuracy of clinical diagnosis of cirrhosis among alcohol-abusing men. Journal of Clinical Epidemiology 1996 49: 1295-1301.

THE OXFORD SYSTEMATIC REVIEW TRAINING PROGRAMME

Systematic reviews which locate, appraise and synthesise the results of relevant research studies are recognised as one of the most useful and reliable tools to assist the practice of evidence-based health care. The programme will train health care professionals in the science and methods of systematic review, and will help them produce a systematic review.

Aim

To increase the production and publication of systematic reviews. Students and collaborative teams will receive training in the principles, methods and practicalities of undertaking a systematic review. Topics will include formulation of research questions, protocol development, literature searching, critical appraisal, data synthesis, reporting, interpretation and project management. Training will be given in relevant software packages.

Who should apply?

Health care professionals and researchers who want to learn more about systematic reviews and to undertake one. Applicants must have an idea of a research question which could be answered. Those most likely to be selected will have a good basic knowledge of the science of medical research, and be able to form a multidisciplinary team. Students will be encouraged to bring their collaborating librarians, information scientists, statisticians and methodologists to attend relevant sessions. Places will be limited to 12 applicants. There will be an emphasis on reviews relating to Primary Care.

Course structure

Most of the formal learning will take place in 12 one-day training sessions. Students will be required to undertake directed pre-session reading and to complete appropriate sections of their systematic review between the sessions. In addition, a limited amount of individual project support will be available from the course tutors throughout the year.

Fees and bursaries

The basic fee for the full course is £1300. Financial assistance with course fees and a limited number of Bursaries are available to pay up to £2500 to cover locum costs where needed. Priority will be given to applications relating to Primary Care, and from employees from the Anglia and Oxford Region.

Course and application dates

The 12 training days will be scheduled between February 1997, and be completed by December 1997. Applications must be submitted by January 22 1997.

For further information contact Jon Deeks at the Systematic Review Unit (tel 01865 227001, e-mail Jon.Deeks@clinical-medicine.oxford.ac.uk). For information about future courses please write to Rochelle Seifas, Project Coordinator: Systematic Review Unit, Centre For Statistics In Medicine, Institute Of Health Sciences, Old Road, Headington, Oxford OX3 7LF

BANDOLIER BACK NUMBERS

Bandolier - the first 20 issues is now out of print, but a new collected volume of *Bandolier 21-34* should be available in the Spring.

Bandolier is distributed free within the NHS, but arrangements differ slightly between regions. In Scotland and Northern Ireland, you have to pay for *Bandolier*. The cost for single subscriptions is £30 a year, but *Bandolier* is able to make substantial reductions for bulk distribution to Health Authorities and Trusts. Contact numbers - page 8.

Non-NHS subscriptions

Bandolier is now being distributed outside the NHS by Hayward Medical Communications. Information on subscriptions and payment from Christine Fortune: Tel 01608 645564, Fax 01608 645645, email: hayward.medical@etgate.co.uk

FAMILY TREATMENT FOR SCHIZOPHRENIA?

Schizophrenia is a serious mental illness with a lifetime risk of about 1% in most countries, including the developing world. Its hallmarks are delusions (false, culturally inappropriate beliefs) and hallucinations (especially hearing voices), with associated abnormal behaviour. The condition sometimes has a good outlook, but often becomes chronic, with relapses and remissions, and a general decline in self-care and the capacity to lead an independent life. A recent systematic review [1] examines whether treating the family as a whole benefits the member with schizophrenia or the family itself.

Do abnormal families cause schizophrenia?

Schizophrenia usually begins in adolescence or early adulthood, so the possible role of the family in the course or even the causation of the illness has long been studied. Families with "high expressed emotion" towards their schizophrenic member (such as criticism, arguments, etc) have higher rates of relapse in the patient, though it remains unclear if emotion causes relapse or vice versa. Nevertheless, randomised trials have been done to see if reducing this expressed emotion by family treatment might help.

Helping schizophrenics by treating their families?

The treatment involves psychotherapy from a doctor, nurse or other professional, aimed at changing behaviour in various ways, such as reducing expressions of anger and guilt, constructing an alliance with carers and improving adverse family atmosphere.

In view of the inherent difficulty of the subject, the number of trials [1] is surprisingly high, perhaps reflecting the popularity of theories (associated with the "anti-psychiatry" movement of the 1960s and 70s) suggesting explanations in family, environment or society for psychotic symptoms. However, the existence of the trials must not be taken as supporting notions such as the "schizophrenogenic mother", which have wrongly led many families to perceive the illness as their fault [2]. The results of the review do not support such simplistic interpretations.

Methods

The review used Cochrane Collaboration methodology, finding trials by methodical electronic and journal hand searching. It has excited wide interest, with notices in the BMJ and in Evidence Based Medicine. The outcomes chosen were dichotomous (yes/no: e.g. comparing odds of relapse on treatment and control using the odds ratio (OR)), since simple statistical methods are available, and used here, to combine ORs from different studies. It is clearly a high quality review, which provides the best available summary of the present evidence on this topic.

Results

Family therapy reduces relapse during the year following treatment: it is necessary to treat at least six families to prevent one relapse at one year (number needed to treat, NNT = 6.5, 95% confidence intervals 4.3 - 14.0. The NNT is worked out from the OR using a simple calculation reported previously in *Bandolier*). There is a similar reduction in re-admission to hospital, and in improvement of compliance with medication. There was no effect on the levels of expressed emotion in the families, or the burden they perceive.

Conclusions

1 Family treatment reduces relapse and rehospitalisation: about 6 families need to be treated to prevent one such event.

2 Family treatment improves compliance with medication.

3 Family treatment does not alter the emotional climate or perceived burden in the family.

Practice points

1 Family treatment helps prevent relapse, but, as delivered in the trials, is expensive. About six families require a large amount of expensive therapist time to prevent one relapse.

2 The benefits of the treatment seem likely to be due to improved compliance with medication (e.g. long acting "depot" injections). Cash-strapped mental health trusts seem unlikely to purchase a family therapy Rolls Royce if feel they can get to the same place on a push bike.

3 Further research into patient (and family) treatment preferences is needed: should they value a talking treatment which has little or no effect apart from increasing compliance, there will nevertheless be a case to provide, if not a Roller, then at least an Austin Allegro.

References:

1 Mari J, Streiner D. The effects of family intervention on those with schizophrenia. In Adams C, Anderson J, De Jesus Mari, eds. Schizophrenia module, Cochrane Database of Systematic Reviews (updated 23 Feb 1996) Available in the Cochrane Library, London: BMJ Publishing, 1996.

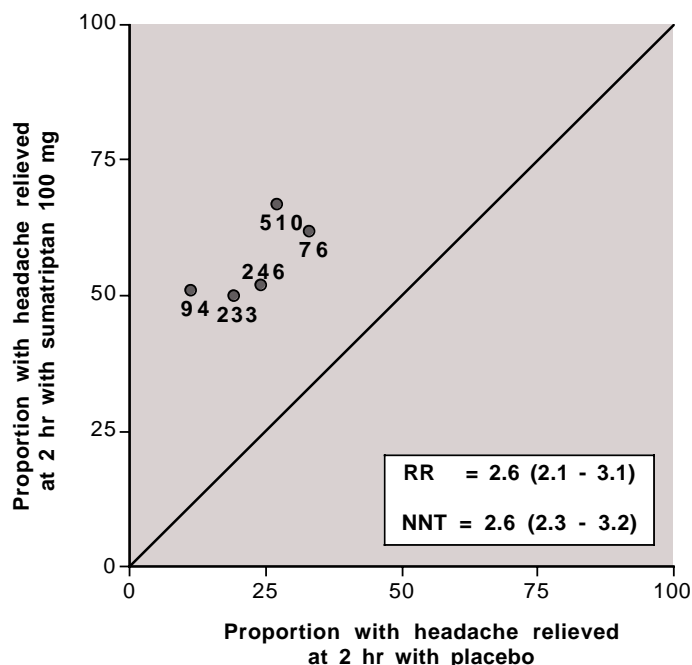2 Amis, Kingsley: Stanley and the Women, Penguin Books, 1980.

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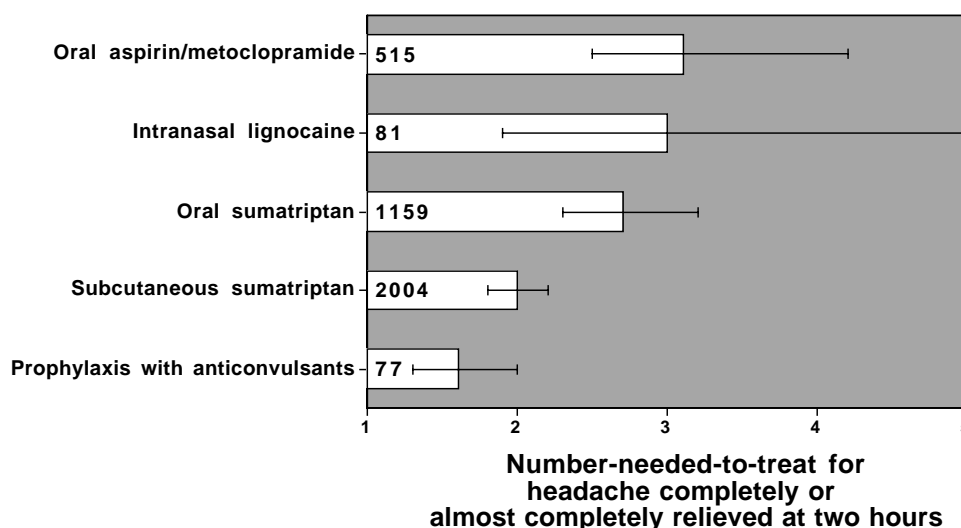
MEA CULPA

Drug treatments for migraine

Bandolier made a mistake in calculating the NNT for oral sumatriptan in issue 33 and is grateful to Peer Tfelt-Hansen of Copenhagen for bringing it to our attention. The NNT should have been 2.7 (2.3 - 3.2) rather than the 4.2 quoted. The corrected L'Abbé plot and league table are shown here, and a corrected version of the article appears on the *Bandolier* Internet pages.

We have also corrected a minor error in the article in *Bandolier* 34 on Howarth's elevators. The numbers in columns 2 and 3 should be reversed.

Randomised trials of oral sumatriptan versus placebo: headache relieved at 2 hours with numbers of patients in active and placebo groups

RR   = 2.6 (2.1 - 3.1)

NNT = 2.6 (2.3 - 3.2)

Proportion with headache relieved at 2 hr with placebo

BOOK REVIEW

Are you confident when asked to compare and contrast the uses, advantages, weaknesses, potential pitfalls and interpretation of case series, surveys, cohort studies, clinical trials, case-control studies, qualitative methods of research and operations research? Can you move with ease between research questions in epidemiology, economics, psychology, sociology and health promotion? When you appraise a research report do you readily identify flaws in study design, data collection, data analysis and interpretation? Do you understand fully the scope of health services research? Is your writing style relaxed, accessible and enlivened by informative examples? If you answered yes to all of these questions then you are either the author of this book or an editor of *Bandolier*. For everyone else interested in the design, conduct and interpretation of health services research this book provides an excellent, readable, practical introduction to the subject.

Douglas Justins
St Thomas' Hospital London

Relative effectiveness of treatments for migraine compared with placebo with total numbers of patients in active and placebo groups

Number-needed-to-treat for headache completely or almost completely relieved at two hours